IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DISTRICT COUNCIL 37 HEALTH & SECURITY PLAN and THE GUARDIAN LIFE INSURANCE COMPANY OF AMERICA, **Plaintiffs** **v.** **MERCK SHARP & DOHME PHARMACEUTICALS SRL and MERCK & CO. INC.,** **Defendants.**	**C.A. No.** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiffs, District Council 37 Health & Security Plan and The Guardian Life Insurance Company of America, individually and on behalf of all others similarly situated, for their complaint against defendants Merck Sharp & Dohme Pharmaceuticals SRL and Merck & Co. Inc. (collectively "Defendants"), upon knowledge as to themselves and their own acts, and upon information and belief as to all other matters, allege as follows:

NATURE OF THE ACTION

1. Singulair is the brand name for the prescription drug montelukast sodium sold by Merck & Co. Inc. under a distribution agreement between it and Merck Sharp & Dohme Pharmaceuticals SRL ("MSD"). Montelukast sodium is a leukotriene antagonist. Leukotriene antagonists "block" the action of leukotrienes, which are chemical substances that can trigger asthma and allergic conditions, on target cells such as those in lung tissues. Singulair is

prescribed to treat asthma and seasonal allergies. Merck & Co. Inc. has FDA approval to sell montelukast sodium pursuant to its NDA No. 20-829.

2. MSD owns all rights, title and interest in U.S. Patent No. 5,565,473 ("the '473 Patent"), which issued on October 15, 1996 for *unsaturated hydroxyalkylquinoline acids as leukotriene antagonists*, in the names of inventors Michel L. Belley, Serge Leger, Marc Labelle, Patrick Roy, Yi B. Xiang and Daniel Guay. MSD acquired the '473 Patent through a series of assignments and name changes from Merck Frosst Canada, Inc. (Merck & Co., Inc. with MSD and its predecessor in interest Merck Frosst Canada are hereafter collectively referred to as "Merck.")

3. Merck obtained its patent on Singulair through a pattern of material and intentional misrepresentations and omissions in its dealings with the United States Patent and Trademark Office (the "PTO"). As alleged below, Merck deceived the PTO by deliberately concealing from the PTO Merck's own critically important prior art, from which Merck's idea for the invention had been derived, and by making deliberately misleading statements to the examiner with regard to prior art. Were it not for that fraudulent and deceptive conduct, the PTO would not have granted Merck's petition for the Singulair patent.

4. Merck has used its fraudulently obtained, invalid and unenforceable patent to eliminate competition by manufacturers of generic montelukast sodium by listing its fraudulently obtained '473 Patent in the FDA's Orange Book, and through sham litigation filed by MSD purportedly to enforce the '473 Patent.

5. By eliminating generic substitutes for Singulair from the market through its Orange Book filing and through sham litigation, Merck has established and maintained an unlawful nationwide monopoly in the market for montelukast. Were it not for Merck's

enforcement of its fraudulently procured patent, Merck's competitors would have obtained FDA approval to market competing generic drugs on or about August 20, 2003, thereby causing prices of montelukast sodium and Merck's market share to decline significantly.

6. Plaintiffs bring this action on behalf of themselves and two Classes of Singulair end-payors. As a result of Defendants' anticompetitive conduct, end-payors of montelukast sodium have been denied the benefits of free and unrestrained competition in the montelukast sodium market. More specifically, Plaintiffs and the Classes have been denied the opportunity to choose between brand-name Singulair and lower-priced generic versions and are being made to pay supracompetitive prices for montelukast.

7. In Count I, Plaintiffs seek a judgment pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of Defendants' unlawful monopolistic practices in violation of §2 of the Sherman Act, 15 U.S.C. §2. Plaintiffs do not seek any relief under §4 of the Clayton Act, 15 U.S.C. § 15.

8. In Count II, Plaintiffs seek damages, penalties, and injunctive relief for Defendants' violations of the state antitrust and/or unfair and deceptive practices statutes.

9. In Count III, Plaintiffs seek equitable remedies based on Defendants' unjust enrichment as a result of the facts alleged herein.

JURISDICTION AND VENUE

10. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331, 1332(d)(2), and 1337(a), and 15 U.S.C. §§ 22 and 26. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a). This Court also has jurisdiction over these actions pursuant to the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. § 1711, *et seq.*, which vests federal district courts with original jurisdiction over any multi-state class action where the aggregate amount in controversy exceeds $5,000,000 and the citizenship of any member of the

class of plaintiffs is different from any defendant. The diversity and amount in controversy requirements of CAFA are satisfied in this case.

11. Venue is proper within this District under 15 U.S.C. §22 and 28 U.S.C. §1391(b) because Defendants are found and transact business within this District, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District. Jurisdiction over all defendants comports with the United States Constitution and 15 U.S.C. §§15, 22 and 26 and the long-arm statute of the State of New York.

INTERSTATE TRADE AND COMMERCE

12. At all relevant times, Singulair was sold, shipped and transported across state lines to United States customers located across the country. MSD manufactures the active pharmaceutical ingredient used in manufacturing Singulair in Barbados and thereafter ships and transports that active pharmaceutical ingredient into the United States pursuant to a distributorship with Merck & Co. Inc.

13. During the Class Period, in connection with the purchase and sale of Singulair, monies as well as contracts, bills and other forms of business communications and transactions were transmitted by Defendants across state lines and national boundaries.

14. During the Class Period, various means and devices were used to effectuate the conspiracy alleged herein, including the United States mail, interstate and foreign travel, interstate and foreign telephone commerce and other forms of interstate and foreign electronic communications. The activities of Defendants alleged herein were within the flow of, and have substantially affected, interstate commerce.

THE PARTIES

A. Plaintiffs

15. Plaintiff District Council 37 Health & Security Plan ("DC 37") is a non-ERISA union-sponsored employee welfare benefit plan subject to the reporting requirements of the New York City Controller's Internal Control and Accountability Directive No. 12. The right to bargain for said welfare benefits is recognized by Section 12-307 of the New York City Collective Bargaining Law. As such, DC 37 is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). DC 37 maintains its principal place of business in New York, NY. DC 37 provides supplemental health benefits, including a prescription drug benefit for over 350,000 participants and beneficiaries in all but one state in the United States. DC 37 is the largest public employee union in New York City.

16. Plaintiff The Guardian Life Insurance Company of America ("Guardian") is a mutual life insurance company organized and existing under the laws of the State of New York. Guardian provides health insurance benefits, including a prescription drug benefit, for an average of 400,000 beneficiaries throughout the relevant period. Guardian's insureds reside and Guardian has made purchases of or reimbursed for purchases of Singulair in all fifty states and the District of Columbia. During the Class Period, as defined herein, Guardian has paid approximately $16 million for Singulair.

B. Defendants

17. Merck & Co. Inc. is a New Jersey corporation with its headquarters located at White House Station, New Jersey. Merck is a global company that researches, develops and markets pharmaceuticals and vaccines. Merck sells its human health pharmaceutical products nationwide primarily to drug wholesalers and retailers, hospitals, government agencies and

managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions.

18. Merck Sharp & Dohme Pharmaceuticals SRL ("MSD") is a corporation organized and existing under the laws of Barbados that maintains its principal place of business at Chancery House, High Street, Bridgetown, Barbados. MSD is a subsidiary of Merck & Co. Inc., and Merck & Co. Inc. purchases montelukast sodium used in Singulair from MSD pursuant to a supply distributorship agreement.

CLASS ACTION ALLEGATIONS

19. Plaintiffs bring this class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, sub-sections 23(a) and 23(b)(2) and/or (b)(3), on behalf of two Classes defined as follows (the "Classes"):

a. Counts I and III ("Nationwide Class"):

> All persons or entities who purchased, paid for and/or reimbursed for Singulair and any generic version thereof in the United States of America and its territories, for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries and for purposes other than resale from August 20, 2003 through the date of the entry by the Court of an order certifying this class (the "Class Period").
>
> Excluded from the Nationwide Class are Defendants, their subsidiaries and affiliates; all government entities (except for government-funded employee benefit plans); all persons or entities that purchased Singulair for purposes of resale, or directly from Defendants or its affiliates; and the judge in this case and any members of his/her immediate family.

b. Count II ("Indirect Purchaser States Class")

> All persons or entities who purchased, paid for and/or reimbursed for Singulair and any generic version thereof in Arizona, California, District of Columbia, Florida, Iowa, Kansas, Louisiana, Maine, Minnesota, Mississippi,

> Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Utah, Vermont, West Virginia, and/or Wisconsin, for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries and for purposes other than resale from August 20, 2003 through the date of the entry by the Court of an order certifying this class (the "Class Period").
>
> Excluded from the Indirect Purchaser States Class are Defendants, their subsidiaries and affiliates; all government entities (except for government-funded employee benefit plans); all persons or entities that purchased Singulair for purposes of resale, or directly from Defendants or its affiliates; and the judge in this case and any members of his/her immediate family.

20. Plaintiffs, on behalf of themselves and all other Indirect Purchaser State Class members, seek declaratory, injunctive and monetary relief against Defendants based on allegations of monopolization of, and an attempt to monopolize, the market for Singulair. Plaintiffs seek class certification pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure as to declaratory and injunctive relief, and Rule 23(b)(3) as to damages.

21. Declaratory and injunctive relief is appropriate under Rule 23(b)(2) because, as alleged herein, Defendants have acted on grounds generally applicable to the Classes, thereby making appropriate declaratory and final injunctive relief with respect to the Classes as a whole.

22. Members of the Classes are so numerous that joinder is impracticable. Plaintiffs believe that the Classes include tens of thousands of members.

23. Plaintiffs' claims are typical of the claims of the members of the Classes. Plaintiffs and all members of the Classes were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for montelukast sodium and were deprived of the benefits of competition from cheaper generic versions of Singulair as a result of Defendants' wrongful conduct.

24. Plaintiffs will fairly and adequately protect and represent the interests of the Classes. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Classes.

25. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving pharmaceutical products.

26. Questions of law and fact common to the Classes include:

a. Whether Defendants' anticompetitive conduct, as alleged herein, violates the Sherman Act;

b. Whether and to what extent Defendants' acts restrained trade, commerce or competition for the sale of Singulair and its generic bioequivalents and prevented or delayed introduction of generic formulations of Singulair in the United States;

c. Whether Defendants obtained, possessed and/or unlawfully used monopoly power over the relevant market for Singulair and its generic bioequivalents;

d. Whether Plaintiffs and the Classes suffered antitrust injury or were threatened with antitrust injury as a consequence of Defendants' unlawful conduct; and

e. The amount of the overcharges or amounts paid by members of the Classes for Singulair over and above the amounts they would have paid or reimbursed for montelukast sodium in a competitive market unaffected by Defendants' unlawful acts as alleged herein.

27. Class action treatment is the superior (if not the only) method for the fair and efficient adjudication of this controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum

simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims which would not be practicable to pursue individually, substantially outweigh the difficulties, if any, that may arise in management of this class action.

28. Defendants have acted and refused to act, as alleged herein, in ways generally applicable to the Class, thereby making final injunctive relief and/or corresponding declaratory relief appropriate with respect to the Classes.

29. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

RELEVANT MARKET

30. To the extent applicable to the claims alleged herein, the relevant product market is the market for the manufacture and sale of montelukast, including Singulair and generic bioequivalent products rated "AB" by the United States Food and Drug Administration (the "FDA").

31. The relevant geographic market is the United States and its territories.

32. At all relevant times, including the present, Defendants' market share in the relevant product and geographic markets was and is 100%.

BACKGROUND ALLEGATIONS

33. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. From 1999 to 2005, however, prescription spending growth slowed because of increased use of generic drugs, an increase in tiered copayment benefit plans, changes in the types of drugs used, and a decrease in the number of drugs introduced. According to IMS Health, the total sale of prescription drugs in the United

States has risen from $239.9 billion in 2004 to $291.5 billion in 2008. During that time, brand name drug prices increased by an average of 21%, while generic drug prices decreased by an average of 12.8%.

A. The Role of Generic Drugs in the Pharmaceuticals Market

34. Generic drugs are drugs that the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is bioequivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating. According to the FDA, a bioequivalent drug rated "AB" may be used and substituted interchangeably with the referenced branded drug. The majority of states use the FDA's "AB" rating of therapeutic substitution as the foundation for generic substitution, either by permitting substitution based on the FDA's Orange Book listing, or by using the FDA's "AB" rating as the basis for cursory administrative approval. At present, thirty-nine states permit substitution of generic products while at least eleven states mandate generic substitution.

35. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be purchased from a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug which has been approved by the FDA is available.

36. Once a physician writes a prescription for a brand-name drug such as Singulair, that prescription defines and limits the market to the named drug or its AB-rated generic equivalents. Only generic drugs that carry the FDA's "AB" rating may be substituted by a pharmacist for a doctor's prescription for a brand-name drug.

37. If an AB-rated generic formulation of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most prescription drug benefit plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by prescription drug benefit plans, the pharmacist will offer the consumer the choice of purchasing the AB-rated generic at a lower price.

38. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. A report prepared by the Government Accounting Office in August 2000 observed that: "Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs." "On average," according to the FDA website, "the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. As additional generic manufacturers market the product, the prices continue to fall, but more slowly. For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower." Generic Competition and Drug Prices, (Page Last Updated: 04/30/2009), U.S. Food and Drug Administration, http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm (last visited July 21, 2009).

39. When generic versions of popular brand-name drugs are launched, the generics quickly capture the bulk of the market, saving consumers billions of dollars. The Federal Trade Commission has stated that, "[a]s a result of price competition, as well as the policies of public

and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of the lower-priced generic product." Federal Trade Commission, *Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry*, July 20, 2006 at 6, *Available at:* http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf. A study released earlier this year by the Generic Pharmaceutical Association based on an independent analysis of data from IMS showed that the use of generic drugs has saved consumers, patients, and healthcare providers $734 billion over the past ten years (1998-2008), with approximately $121 billion in savings in 2008 alone.

40. Brand-name drug manufacturers typically respond to generic competition by lowering their prices. Studies have also shown that the average price of brand-name drugs facing generic competition is less than the average price of brand-name drugs without generic competition.

41. Generic competition provides a substantial benefit to the public in the form of lower drug costs.

B. The Federal Procedure for Approval of Generic Drugs

42. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, approval from the FDA is required before a company may begin selling a new drug. Premarket approval for a new drug, often referred to as a "pioneer drug," must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use.

43. New drugs that are approved by the FDA for sale in the United States are often covered by patents, which provide the patent owner with the exclusive right to sell that new or

pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §355 (the "Hatch-Waxman Act").

44. The FDA maintains and publishes an official listing of all prescription drugs approved for use in the United States, any patents covering those drugs and all generic equivalents, if any. This list is known as the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

45. In 1984, Congress enacted the Hatch-Waxman Act to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. The Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA") that incorporates by reference the safety and effectiveness data developed and previously submitted by the company that manufactured the original, pioneer drug. An ANDA may be filed by a generic drug manufacturer where a patent for a branded drug listed in the Orange Book has not expired. The generic drug manufacturer must file an ANDA certification seeking approval to sell the new generic drug and must notify the patent holder of the pioneer drug of the filing. Four types of certifications are available:

I. The brand name manufacture has not filed patent information with the FDA (a "Paragraph I Certification");

II. The patent or patents listed in the Orange Book have expired (a "Paragraph II Certification");

III. The patent or patents listed in the Orange Book will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III Certification"); or

IV. The patent or patents listed in the Orange Book are invalid or not infringed by the generic manufacturer's product (a "Paragraph IV Certification").

See 21 U.S.C. §355(j)(2)(A)(vii). The requirements of the Hatch-Waxman Act with regard to Orange Book filings and Paragraph IV Certifications have the purpose and effect of enforcing lawfully-obtained patents that are subject to Orange Book filings and discouraging competing drug manufacturers from selling competing products until litigation with regard to patent validity has been commenced and resolved.

46. The Hatch-Waxman Act provides an economic incentive to the manufacturer of the first generic drug to file an ANDA with a Paragraph IV Certification (an "ANDA(IV)") for a particular generic drug: a 180-day statutory period of market exclusivity during which time the generic manufacturer has the right to market its drug free from other generic competition.

47. Upon receiving notification of a Paragraph IV Certification from an ANDA applicant, the branded drug owner has forty-five days under the Hatch-Waxman Act to initiate a patent infringement suit against the ANDA applicant if the branded drug owner believes the generic product would infringe on a valid patent for the branded drug. If no action is initiated within forty-five days, the process for FDA approval of the generic product continues without delay. However, if a patent infringement suit is commenced within the forty-five-day window, FDA final approval of the ANDA is automatically postponed until the earliest of the expiration of the patent, the expiration of thirty months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement or patent invalidity.

48. Thus, pioneer drug patent holders need only file a patent infringement lawsuit within forty-five days of receipt of a Paragraph IV Certification in order to block an ANDA applicant's generic drug from entering the market for up to thirty months. A generic ANDA filer

cannot enter the market within that period unless the patent is held to be invalid, unenforceable, or not infringed.

49. Even if the patent lawsuit commenced by the branded drug company is still ongoing after thirty months, the Hatch-Waxman Act permits the FDA to approve an ANDA after the expiration of the thirty-month delay. Thereafter, the ANDA applicant is free to market its generic product in the United States, even if the patent infringement lawsuit is unresolved.

50. Unlike "final" approval, the FDA is free to grant the ANDA applicant "tentative" approval of an ANDA once the FDA determines that all the criteria for ANDA "final" approval (except the expiration of the thirty- month delay) have been satisfied.

C. The Procedure for Lawfully Obtaining a Patent

51. The PTO was established to administer the United States patent system. The PTO examination corps includes supervisory patent examiners ("SPEs"), primary examiners and examiners with full, partial and no signature authority. These examiners, particularly the SPEs and those with signature authority, are persons who have spent time working as examiners in the subject technology, searching the prior art in that technology, and developing an acquaintance with the published art.

52. Upon receipt of a patent application, the PTO checks the application to ensure it meets all formal requirements. The PTO assigns an examiner to review the application and determine whether the invention disclosed in the application meets four substantive requirements, including:

a. subject matter, *i.e.*, that the type of technology is one that can be patented, and has utility or industrial application; only one patent may be granted for a single invention, 35 U.S.C. §101;

b. that the invention has not been previously disclosed to the public, in what is referred to in the patent field as "prior art," 35 U.S.C. §102;

c. that the invention would not have been obvious to "one skilled in the art" based upon what is contained in the prior art, even if the invention is not specifically disclosed in the prior art, 35 U.S.C. §103; and

d. that the invention is properly disclosed in the application such that one skilled in the art can make and use it, the application sets forth the "best mode" contemplated by the inventor for carrying out the invention, and the specification contains a written description of the invention which is commensurate with the full scope of the claims, 35 U.S.C. §112.

53. After the filing of the patent application, of the PTO examiner and the applicant exchange correspondence in an attempt to assess the patentability of the invention. This process is termed the "prosecution" of the application. As part of the prosecution, applicants are required to submit to the PTO the most relevant prior art of which they are aware. In view of prior art cited by the applicant, and any prior art the examiner himself may have found, the examiner determines whether in his judgment any of the prior art references anticipate any claims under 35 U.S.C. §102 (*e.g.*, whether any single prior art reference individually discloses every element recited in the claims). The examiner also determines whether in his judgment a reference, or a group of references, would have rendered the claim obvious to persons of ordinary skill in the art at the time when the invention was made pursuant to 35 U.S.C. §103.

54. Next, the examiner writes a letter known as a "Patent Office Action," in which claims in the application often are initially rejected. In their actions upon applications for patents, examiners are duty bound, as best as they can under the constraints of their very limited

resources, quotas and schedules, to reject disclosures that fail to enable those skilled in the art to practice and use the invention, and to reject claims that do not distinctly point out the invention and define non-obvious new subject matter and otherwise fulfill the requirements of 35 U.S.C. §§102, 103, 112, and other relevant provisions of Title 35.

55. The applicant may argue for allowance of the application with or without amendments to the claims. The applicant may argue patentability over a reference and may point out perceived distinctions between patent claims and any references cited. The applicant also may submit a sworn declaration or affidavit presenting technical data or arguments. The amendments and arguments made by the applicant are typically made in writing. To facilitate prosecution of the patent, the applicant may interview the examiner and make arguments either by phone or in person. The agreements made at such meetings are required to be summarized in writing. This summary then becomes part of the prosecution history of the patent.

56. The prosecution of the application continues until the examiner either issues a "Notice of Allowance" allowing all of the uncanceled claims or a "Final Action" rejecting the disclosure or the claims that have not been allowed by the examiner. The "Final Action" usually is not truly the final action of the examiner. Rather, a limited further prosecution of the application may be permitted before the examiner.

57. Following the notice of allowance, a patent-issue fee is due. After that payment, the patent is printed and published on its issue date so that the public has access to the disclosure of the invention and its claims. The examiner's file of prosecution in the application, previously kept confidential, at least at the time of these applications, is then opened for public inspection and copying.

D. An Applicant's Duty of Candor to the PTO

58. Under the rules of the PTO, an applicant has a duty of candor and good faith to the PTO. This includes a duty to disclose all known information material to the patentability of the invention, including but not limited to all known prior art:

> A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentablity as defined in this section…

See 37 C.F.R. § 1.56(a). Regulations governing the PTO further provide that:

> information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.

Id. at § 1.56(b).

59. A primary reason for the duty of candor and the specific requirement that material art be disclosed to the examiner is that due to the high number of patent applications received and the limited number of PTO examiners, the patent examiner has very limited time available to read and understand the invention, search the art, issue official actions and otherwise correspond and/or meet with the inventor's attorney.

60. Chemical applications, like those as are relevant here, are especially difficult to search. The claims can include hundreds or even thousands of compounds. Prior inventors in the art may have used different chemical nomenclature. Thus, the examiner must rely upon the inventor and the inventor's attorneys to be forthcoming and to bring to the attention of the PTO the prior art of which they are aware and to properly characterize the prior art. This is particularly true when the inventors are part of a large research organization, such as Merck, where scientists typically follow the relevant literature closely, are deeply versed in its content, and write or publish much of the pertinent scientific literature.

61. The presentation of data to the patent examiner in a misleading fashion violates the duty of candor and good faith and can constitute inequitable conduct or fraud on the PTO. Such conduct can include presenting inaccurate, incomplete or misleading information, such as deceptively comparing the claimed invention to prior art which is not the closest prior art of which the inventor is aware, or withholding unfavorable information.

62. Issues of fraud, inequitable conduct and violations of the duties of disclosure to the PTO can render a patent invalid and/or unenforceable. However, under established PTO procedure, such issues cannot be re-opened for examination by the PTO in reexamination proceedings.

E. Merck's Inequitable Conduct and Fraud on the PTO to Obtain the '473 Patent

63. The '473 Patent issued from the following series of patent applications: U.S. Appl. Ser. No. 08/392,592 ("the '592 Application"), which is a continuation of U.S. Appl. Ser. No. 07/774,414 ("the '414 Application"), now abandoned, filed Oct. 10, 1991, which is a continuation-in-part of U.S. Appl. Ser. No. 741,888 ("the '888 Application"), filed Aug. 8, 1991, now abandoned, which is a continuation-in-part of U.S. Appl. Ser. No. 596,887 ("the '887 Application") filed Oct. 12, 1990, now abandoned. A continuation-in-part application

incorporates new matter into an application while a continuation application does not. Each application, as required by law, contains an oath by each of the named inventors in which each declares under penalty of fine and/or imprisonment, that he is an original, first and joint inventor of the subject matter claimed in the application and that the statements made in the oath are true. Each inventor also acknowledges his obligation to disclose information material to the application to the Patent Office. A separate oath was signed for each of the applications identified above.

64. During its efforts to procure the '473 Patent from the PTO, Merck deliberately engaged in inequitable and fraudulent conduct in its statements and submissions to the PTO. Merck's inequitable and fraudulent misrepresentations and omissions were intended to deceive and did in fact deceive the PTO, and resulted in the issuance by the PTO, on October 15, 1996, of the '473 Patent.

65. At the time when the '887, '888, '414 and '592 Applications were filed, PTO Rule 56 required an applicant (including inventors, attorneys, agents and others involved in the prosecution of a patent application) to disclose to the PTO information they are aware of **"**which is material to the examination of the application." Such information includes any prior art which may form the basis for a rejection under 35 U.S.C. §102 (novelty) or 35 U.S.C. §103 (obviousness). PTO Rule 56 further requires, when an applicant files an application that relates to an earlier filed application, that the applicant disclose any information relevant to the subject matter of the claim of which the applicant learned between the time of filing of the original application and the time of the subsequent application.

66. Under §103, an invention cannot be patented if it would have been obvious to "a person having ordinary skill in the art" in light of the "prior art." Prior art is a term of art that

includes, among other things, material patented or described in a printed publication anywhere in the world prior to the invention by the applicant.

67. Two highly material articles written by Dr. Robert Young, a member of the research team at Merck Frosst Center for Therapeutic Research ("MF-CTR"), published prior to the filing of the '887 Application, were deliberately concealed by Merck rather than being disclosed to the PTO in the '887, '888, '414 or '592 Applications. These articles were: Robert N. Young, "Structural Analysis of Sulfido-Peptide Leukotrienes: Application to the Design of Potent and Specific Antagonists of Leukotriene D_4," Advances in Prostaglandin, Thromboxane, and Leukotriene Research, 1989, vol. 19, pages 643-646 ("Young 1989"), published well over one year prior to the filing of the '887 Application; and Robert N. Young, "The Development of New Anti-Leukotriene Drugs: L-648,051 and L-649,923, Specific Leukotriene D_4 Antagonists," Drugs of the Future, 1988, vol. 13, pages 745-759, ("Young 1988"), published in 1988, almost two years prior to the '887 Application.

68. The author of these withheld references, Dr. Young, was an MF-CTR researcher. The articles were reviewed and approved for publication by Gabriel Lopez, the same Merck & Co. Inc. attorney who drafted the '473 patent applications and who handled most of the prosecution of the applications.

69. Dr. Young also presented the same material to his fellow MF-CTR researchers, including inventors named in the '473 Patent, prior to their alleged invention. A primary inventor named in the '473 Patent has conceded in deposition testimony that key insights behind the purported invention in the '473 Patent first occurred to Merck scientists either during that presentation or shortly thereafter, and were prompted directly by the presentation made by Dr. Young. Those insights occurred to the inventors then for the simple reason that they were

obvious from the prior art of Dr. Young that was presented at that time. Upon information and belief, the inventors have conceded, in depositions in pending patent infringement litigation, that they believe the Young references are highly relevant to the '473 Patent. Nevertheless, Merck intentionally concealed from the PTO both of Dr. Young's prior art references from which key concepts behind the purported invention of the '473 Patent directly originated.

70. Both articles by Dr. Young suggest substitution of a secondary or tertiary alcoholgroup for the primary alcohol – a central issue during prosecution of the '473 Patent.

71. A third, also highly material reference was edited by another MF-CTR researcher, Dr. Joshua Rokach, and includes chapters written by other MF-CTR researchers. Joshua Rokach, Ed., Leukotrienes and Lipoxygenases: Chemical, Biological and Clinical Aspects, Bioactive Molecules volume II, pages 490-491, Elsevier, was published in 1989 ("Rokach 1989"). Although published within one year of the '887 application, it is prior art to the new material, including the montelukast compound, disclosed in the '888 and '414 continuation-in-part applications.

72. While the Rokach 1989 reference is mentioned in the patent specification, a copy was not provided to the examiner despite requests for copies of all the references discussed in pages 1-3 of the specification. *See* Office Action dated March 18, 1991.

73. In statements made by Merck during its prosecution of the '473 Patent about the Rokach reference, Merck deliberately presented a misleading description of a text solely relating to leukotrienes, and failed to identify the extensive work in the Rokach reference on the development and design of leukotriene antagonists.

74. These three pieces of prior art, with which both the inventors and Merck itself were intimately familiar, are all critical to the montelukast invention, since montelukast can be

constructed using the steps laid out in the Young publications using the starting compound described in Rokach.

75. Merck's intent to mislead and defraud the PTO, in choosing not to cite its own prior art publications from which key concepts behind the '473 patent had been directly derived by the Merck inventors, is clear from the prosecution of the four applications leading to the issuance of the '473 patent.

a. In the first PTO Office Action, the examiner cited four new references (Huang, Mohrs, Young and Mohrs II) and two foreign references identified in the '887 Application, stating that it would have been obvious to combine the heterotetrahydrocarbazole moieties taught in the acknowledged prior art as leukotriene inhibitors with the quinolin moieties taught in Huang, Mohrs, Young and Mohrs II.

b. In its response to the Office Action (dated June 18, 1991), Merck misleadingly asserted that "Young, *et al.'s* compounds differ significantly from the present invention in that the Q side chains is attached directly to the benzene ring by a heteroatom; whereas the present compounds have the Q side chains insulated from the benzene ring by a saturated carbon atom. Furthermore, the compounds of Young, et al. have one polar Q per side-chain, whereas the present compounds have two such groups." Merck went on further to assert that "the present compounds differ from EP 318,093 in that Q 2 is a secondary or tertiary alcohol or amine." Merck made these deceptive and misleading statements despite knowing that Merck's own prior art in the Young 88, Young 89 and Rokach references

had fully revealed and disclosed the same concepts that Merck claimed distinguished the '473 patent from other prior art.

c. The examiner made a similar rejection in the first Office Action in the '888 Application and rather than respond, Merck abandoned the application.

d. At no time during the prosecution of the '887, '888, '414 or '592 applications did Merck disclose the Young 1988 or the Young 1989 publications or accurately describe the teachings of the Rokach publication – all of which contain teachings that illustrate the distinctions heavily emphasized by Merck in the statements that it made to the PTO to overcome the PTO's initial rejection of the claims in the '473 Patent.

76. In stating to the PTO that the prior art cited by the examiner does not disclose the claimed combination of elements, even while being aware that the very same combination of elements was fully disclosed in Merck's own, much more relevant prior art (which Merck concealed), Merck intended to and did mislead and deceive the PTO and obtain the '473 Patent by fraud. Merck's intent to mislead and defraud the PTO is further evidenced by Merck's failure to disclose an April 1988 Abstract written by a group of Merck employees including Michel Belley and Serge Leger, two of the named inventors of the '473 Patent. According to Dr. Rokach, a Merck employee at the time and another co-author of the abstract, the abstract disclosed the development and structure of the L-660,711 and described it as "extremely potent *in vitro* (PA_2 = 9.4) and binds to the LTD_4 receptor with almost equal affinity to its natural ligand. L-660,711 is also very potent *in vivo*, against LTD_4 and antigen challenge showing excellent bioavailability and duration of action." The Abstract is identified as Zamboni, R.;

Belley, M.; Champion, E.; Charette, L.; DeHaven, R.; Frenette, R.; Ford-Hutchinson, A.W.; Gauthier, J.Y.; Jones, T.R.; Leger, S.; MacFarlane, C.S>; Masson, P.; Piechuta, H.; Pong, S.S>; Rokach, J.; Williams, H.; and Young, R.N.; Taipei Conference on Prostaglandin and Leukotriene Research, Taipei, Taiwan, April 22-24, 1988, Abstract Book p. 37 (the "Taipei Abstract") and cited as the source of this information in Rokach '89.

77. As named inventors of the '473 Patent, Belley and Leger each signed an inventor's oath in which each acknowledged his sworn obligation to disclose information "which is material to the examination of the application." In direct violation of those oaths, neither the Taipei Abstract nor Dr. Rokach's disclosure of the contents of the Abstract was disclosed to the PTO.

78. Even though Young made substantial contributions to the invention claimed in the '473 Patent, Merck twice omitted to name Young as an inventor of the patent, first when initially applying for the patent, and then a second time when Merck petitioned to correct the inventorship specified in the patent. Had Young been named in the patent applications as one of the inventors, it would have enhanced the possibility that the PTO might independently have discovered Young's prior art. On information and belief, Merck omitted Young's name from the listed inventors in order to facilitate its effort, as described above, to conceal Young's prior art from the PTO and to obtain the '473 Patent by fraud.

79. The PTO examiner would not have allowed the claims of the '473 Patent if Merck's own prior art had been disclosed to him by Merck in its applications for the patent, or if Merck had not made its intentionally deceptive and misleading assertions to the PTO about other prior art that had been uncovered by the examiner. Upon information and belief, the inventors of the '473 Patent have specifically admitted in deposition testimony that the Young 1989

publication would have been important and material to the examiner in deciding whether to grant the '473 Patent. In addition, the PTO examiner's initial rejection of the patent application was overcome only by arguments made by Merck, seeking to distinguish other prior art, that were not true as to Merck's own prior art that had been deliberately concealed from the PTO.

80. A Request for Reexamination of the '473 Patent has been granted by the U. S. Patent and Trademark Office. However, issues of fraud, inequitable conduct and violations of the duty of disclosure to the PTO will not be presented or discussed in that reexamination, because the Manual of Patent Examination Procedure Sections 2014 and 2258 clearly state that such issues are outside the scope of a reexamination proceeding under 35 USC 302-307 and 37 CFR §1.552. MPEP 2217 also states that such issues "will not be considered when making the determination of the request [for reexamination] and should not be presented in the request."

81. Merck not only procured the '473 Patent by inequitable conduct and fraud, it then listed that fraudulently-obtained patent in the FDA's Orange Book with the knowledge that the '473 Patent was invalid and unenforceable by virtue of that fraud, and with the intent and effect of enforcing its fraudulently-obtained patent and thereby preventing competition in the relevant market. The FDA's role in the patent listing process is purely ministerial and does not constitute "government petitioning" that could give rise to a defense of immunity pursuant to the *Noerr-Pennington* doctrine.

82. But for Merck's fraud on the PTO, the '473 Patent would not have issued. With no '473 Patent issuing, Merck was entitled to only five years of marketing exclusivity from the date of FDA approval of Singulair on February 20, 1998. As a "New Chemical Entity," Merck received five years marketing exclusivity, or "NCE" exclusivity, that expired on February 20, 2003. 21 USC §355(a)(3)(E)(ii) and 355(j)(5)(F)(ii). As no patent would have issued, no such

patent could be wrongfully listed with the FDA. With no patent listed with the FDA for Singulair, generic competitors would have been eligible to file Paragraph I certifications (no applicable patent) with their ANDAs seeking approval for a generic Singulair. With only NCE exclusivity in effect, Teva and other generic applicants could have filed ANDAs with Paragraph I certifications as soon as February 20, 2003. FDA ordinarily approves or disapproves an application within no more than 180 days of its acceptance, as is reflected in the governing statutory language. 21 USC §355(j)(5)(A). Per FDA internal policies and procedures, these Paragraph I certifications are given the highest priority. FDA MAPP 5240.3. Thus, FDA would have given these applications their highest priority, and would have approved the applications in a much shorter review time than in reality, and as early as mid-August, 2003. But for Merck's misconduct, one or more competitors would have already begun marketing AB-rated generic versions of Singulair.

F. Merck's Improper Listing of the '473 Patent in the Orange Book

83. As described above, Merck obtained the '473 Patent by willful fraud on the PTO.

84. As the '473 Patent was fraudulently obtained, it is unenforceable.

85. As a wrongfully obtained and unenforceable patent, the '473 Patent was not eligible for listing in the FDA Orange Book at the time Merck so listed it.

86. As Merck knowingly listed an ineligible patent in the Orange Book, Merck has deliberately and knowingly misused the FDA's Orange Book listing process in an effort to exclude competition for Singulair.

87. But for Merck's unlawful listing of the '473 Patent in the Orange Book, Teva would have filed a Paragraph I certification with its ANDA for montelukast sodium, alleging that no patents were listed for that product. Under the terms of the statute, a Paragraph I certification is not an act of infringement, and Merck has no basis upon which to sue.

88. Thus, but for Merck's unlawful listing of the'473 Patent, generic competition for Singulair should again have entered pursuant to the scenario explicated in Paragraph 82 or otherwise.

G. Merck's Filing of a Sham Lawsuit

89. In December 2006, Teva filed ANDA No. 78-605 for 10-mg montelukast sodium. Teva's ANDA contained a Paragraph IV certification to the '473 Patent, asserting that the '473 Patent is invalid, unenforceable, and/or non-infringed. As the first generic company to file a Paragraph IV certification to this patent, Teva is entitled to the accompanying 180 days of marketing exclusivity provided for in the Hatch-Waxman Act.

90. In early 2007, Teva filed ANDA No. 78-723 with the FDA, seeking approval to market generic montelukast sodium tablets in 4-mg and 5-mg dosages. Teva's ANDA for these dosages also contained a Paragraph IV certification, asserting that the '473 Patent is invalid, unenforceable, and/or non-infringed. As the first generic company to file a Paragraph IV certification to this patent, Teva is entitled to the accompanying 180 days of marketing exclusivity provided for in the Hatch-Waxman Act.

91. In accordance with 21 U.S.C. §355(j)(5)(B), Teva sent Merck a Paragraph IV certification notification letter in April 2007.

92. On May 14, 2007, Merck filed suit against Teva, alleging that the Paragraph IV certification was an act of infringement, thereby invoking the Hatch-Waxman Act's automatic 30-month stay. This stay remains in effect as of the date of this filing and will expire on or around November 2009.

93. Merck filed the complaint claiming infringement of the '473 patent by Teva with actual knowledge that the '473 Patent had been procured by fraud on the PTO and was invalid

and unenforceable, and with the anti-competitive purpose of delaying competition in the market for Singulair and its generic equivalent.

94. At the time when Merck filed the patent infringement complaint against Teva, Merck knew or should have known that the '473 Patent was invalid under one or more provisions of Title 35, United States Code, including 35 U.S.C. §103(a).

95. At the time when Merck filed its patent infringement complaint against Teva, Merck knew or should have known that the '473 Patent was unenforceable because of inequitable conduct before the PTO during prosecution of the applications leading to the '473 Patent.

96. At the time when Merck filed its patent infringement complaint against Teva, Merck lacked a good faith basis for believing that Teva had infringed any valid claim of the original '473 Patent.

97. Merck brought its infringement action against Teva for the improper purpose of delaying FDA approval of Teva's ANDA, and thereby preventing Teva from entering the market for montelukast sodium as a generic competitor to Singulair and preventing Teva from providing generic competition for Merck's Singulair.

98. On May 21, 2009, the FDA granted tentative approval to Teva's ANDA 78-605 for 10-mg montelukast sodium tablets, and on June 25, 2009 the FDA granted tentative approval to Teva's ANDA 78-723 for 4-mg and 5-mg montelukast sodium tablets. The FDA stated that it could not grant final marketing approval to those applications because the sham patent infringement litigation remains pending and the 30-month stay under the Hatch-Waxman Act has not yet expired. The FDA stated it was otherwise satisfied that Teva's ANDAs met all of the FDA's requirements for final marketing approval.

99. Merck's conduct with regard to the filing of litigation against Teva had wide-ranging impact on other generic competitors.

100. Roxane Laboratories, Inc. ("Roxane") is a manufacturer of generic pharmaceutical products with its headquarters in Columbus, Ohio. Subsequent to Teva's filing of ANDAs for montelukast sodium with Paragraph IV certifications to the '473 Patent, Roxane also filed an ANDA for the 10-mg strength, also containing a Paragraph IV certification. On June 16, 2009, Roxane received tentative approval for its ANDA for 10-mg montelukast sodium. But for Merck's anticompetitive conduct, this approval would have been final approval, permitting Roxane to immediately market a generic form of Singulair. This delay of final approval has caused Plaintiffs to be further overcharged for purchases of Singulair and its generic equivalents.

101. Mylan Laboratories, Inc. ("Mylan") is a manufacturer of generic pharmaceutical products with its headquarters in Canonsburg, PA. Subsequent to Teva's filing of ANDAs for montelukast sodium with Paragraph IV certifications to the '473 Patent, Mylan also filed its ANDA, also containing a Paragraph IV certification to the '473 Patent. Mylan received tentative approval to market 10-mg montelukast sodium on May 27, 2009, and received tentative approval to market 4-mg and 5-mg montelukast sodium on June 25, 2009. But for Merck's anticompetitive conduct, Mylan would have received final approval, rather than tentative approval, on those dates, and would have been permitted to begin marketing generic forms of montelukast sodium at that time. This delay of final approval has caused Plaintiffs to be further overcharged for purchases of Singulair and its generic equivalents.

102. Merck's unlawful conduct caused the ANDA approval process to be delayed by the FDA and caused Teva to divert its resources from its ANDA application and to expend

substantial resources on litigation. Absent the patent lawsuit, Teva, Roxane, Mylan, and the FDA would have had reason to, and would have, focused and directed more of their limited resources into the ANDA approval process for generic montelukast sodium, and sooner than they actually did. Such focus and resources would have brought earlier FDA approval and marketing of generic montelukast sodium by Teva, Roxane, and Mylan. Upon information and belief, absent a 30-month stay, both Teva and FDA would have been incentivized to fast-track the approval of the ANDA, FDA would have issued a final approval more rapidly than they did in actuality, and as soon as 180 days after filing. The 30-month stay is not scheduled to expire until November 2009.

103. By preventing Teva (the first ANDA filer) from obtaining final FDA approval, Merck has created a bottleneck by which Roxane and Mylan are also excluded from the relevant market. By statute, Roxane and Mylan cannot come to market until 180 days after Teva does so. Thus, the anticompetitive scheme has effectively kept out three potential generic competitors in a market in which generic entry causes immediate, rapid, and in most cases automatic, generic substitution.

104. As a result of Defendant's filing of sham litigation, Plaintiff and the Class have continued to overpay for their purchases of branded and generic forms of Singulair. But for the filing of sham litigation, there would be no accompanying 30-month stay. Upon information and belief, absent a 30-month stay, both Teva and FDA would have been incentivized to fast-track the approval of the ANDA, and would have issued a final approval after the 180 day review period mandated by statute. Thus, but for the sham litigation, Teva would have received final approval as early as August 2007 (180 days after filing), and in any circumstance, substantially earlier than the actual date of tentative approval that occurred in May 2009. As a result,

Plaintiffs and the Class continue to be overcharged by paying higher prices than would have prevailed in the absence of Defendant's unlawful conduct.

EFFECTS ON COMPETITION

105. Merck's scheme to delay the introduction into the U.S. marketplace of any generic version of Singulair has caused Plaintiffs and the Class to pay more than they otherwise would have paid for montelukast sodium.

106. As noted, generic versions of a brand-name drug are initially priced significantly below the brand-name drug. As a result, upon generic entry, purchasers rapidly substitute generic versions of the drug for some or all of their brand purchases. As more generic manufacturers enter the market, prices for generic versions of a drug decrease further because of competition among the generic manufactures. This price competition enables all purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name drug manufactures have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial overcharges from that delay.

107. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Singulair. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their montelukast sodium purchases. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, purchasers, such as Plaintiffs, would have paid less for montelukast sodium by (a) substituting purchases of less-expensive, generic montelukast sodium for their purchases of more-expensive branded Singulair, (b) receiving discounts on their remaining branded Singulair purchases, and (c) purchasing generic motelukast sodium at lower prices sooner.

108. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

MONOPOLY POWER

109. At all times referenced herein, Merck has had monopoly power with respect to its Singulair brand. Merck has had at all times the power to maintain the price of Singulair at supra-competitive levels profitably, without losing substantial sales.

110. Significant, non-transitory price increases by Merck to Singulair have not caused a significant loss of sales to other products.

111. Merck sells Singulair at prices well in excess of marginal costs and enjoys high profit margins.

112. Merck has the power to exclude competition.

TOLLING OF THE STATUTE OF LIMITATIONS

113. The statute of limitations did not begin to run until the date when Plaintiffs discovered, or with reasonable diligence should have discovered, both their injury and the cause of their injury. At no time prior to more than four years before filing this Complaint did a reasonable means exist by which Plaintiffs here could have discovered Merck's fraud on the PTO. Defendants' anticompetitive conduct was undertaken in a manner designed to conceal Defendants' wrongdoing from disclosure. Indeed, Defendants sought to conceal their wrongdoing from the PTO itself. As a result, Plaintiffs had no means of acquiring adequate information to provide sufficient notice of Defendants' intentional misconduct more than four years prior to filing the Complaint.

114. Defendants' unlawful conduct before the PTO was based on fraud, and Defendants have fraudulently concealed the existence of the anticompetitive behavior alleged

herein. Defendants' fraudulent actions were self-concealing. Moreover, Defendants affirmatively concealed the existence of their unlawful conduct by, among other things, engaging in the misrepresentations detailed above, and maintaining sham litigation based on a patent that Defendants knew was invalid and unenforceable.

115. As a result of Defendants' concealment, Plaintiffs cannot reasonably be expected to have filed this lawsuit sooner. Defendants are, therefore, estopped from asserting the statute of limitations as a defense to any of Plaintiffs' claims. The statute of limitations in this matter was tolled due to Merck's fraudulent concealment.

CLAIMS FOR RELIEF

COUNT I
FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 1 AND 2 OF THE SHERMAN ACT

116. Plaintiffs repeat and re-allege the preceding and subsequent paragraphs as though set forth herein.

117. Section 2 of the Sherman Act, 15 U.S.C. § 2, provides in pertinent part that:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony…

118. Defendants knowingly and willfully engaged in a course of conduct designed to obtain and extend their monopoly power in the relevant market. As described above, Merck's '473 Patent was obtained through an extensive pattern of material, intentional misrepresentations and material, intentional omissions in Merck's communications with the PTO, including but not limited to the following:

a. Intentionally withholding prior art of which Merck was aware, including but not limited to Merck's own prior art from which Merck's own scientists had obtained key ideas behind the '473 Patent, with the result that these prior art references were not considered by the examiner;

b. Intentionally making misleading and deceptive statements to the PTO that other, less relevant prior art did not teach or suggest the presence of a secondary or tertiary alcohol group, with the result that the examiner was led to believe mistakenly that all of the claimed compounds were distinguishable from the prior art by the presence of a secondary or tertiary alcohol group, and thus were patentable over the prior art; and

c. Intentionally making misleading and deceptive statements about the Rokach 1989 reference and failing to provide a copy of this reference in response to the examiner's request.

119. Each of the foregoing misrepresentations and omissions was knowingly and willfully made by Merck with an intention to deceive and to mislead the patent examiner and the PTO.

120. The patent examiner and the PTO justifiably relied upon each of the foregoing misrepresentations and omissions by Merck in granting the '473 Patent. Were it not for the foregoing misrepresentations and omissions by Merck, the '473 Patent would not have been granted.

121. Merck knew at least as early as March 1991 that the '473 Patent was invalid for, *inter alia*, obviousness under 35 U.S.C. § 103 and was unenforceable based on inequitable conduct before the PTO during prosecution.

122. By reason of the foregoing facts, at the time when MSD sought to enforce the '473 Patent by filing it in the Orange Book and through its patent infringement litigation against Teva, Merck knew that the '473 Patent was invalid and unenforceable.

123. No reasonable litigant in Merck's position at the time of its suits with Teva could have expected to secure a favorable outcome in Merck's patent infringement litigation against Teva, in light of the facts referenced above. Merck's patent litigation against Teva was therefore a sham.

124. Merck's litigation against Teva concealed an attempt to interfere directly with Teva's sale and marketing of a generic version of Singulair, was intended by Merck to serve as an anticompetitive weapon against Teva, and was intended by Merck to serve anticompetitive purposes rather than genuinely to vindicate a lawfully-obtained patent.

125. Through its frauds on the PTO, its Orange Book filing and its sham litigation against Teva as alleged above, Merck unlawfully monopolized the market for montelukast. Had Merck not fraudulently obtained and enforced its patent as described in detail above, generic competitors would have obtained FDA approval to sell montelukast sodium nationwide in or about August 2003, resulting in greatly reduced prices for montelukast.

126. Defendants intentionally and wrongfully maintained their monopoly power with respect to Singulair in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Nationwide Class paid artificially inflated prices for their Singulair purchases.

127. Plaintiffs and members of the Nationwide Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of paying higher prices for their Singulair purchases than they would have paid in the absence of those violations.

This is the sort of injury that antitrust laws were designed to prevent and flows from that which make Defendants' conduct unlawful. Plaintiffs are the proper entity to bring a case concerning this conduct.

128. Plaintiffs and the members of the Nationwide Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Section 2 of the Sherman Act.

129. Plaintiffs and the members of the Nationwide Class further seek injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT II
FOR COMPENSATORY AND MULTIPLE DAMAGES, PENALTIES, AND DECLARATORY AND INJUNCTIVE RELIEF, UNDER STATE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES

130. Plaintiffs repeat and re-allege the preceding and subsequent paragraphs as though set forth herein.

131. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

e. Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.01 *et seq.*;

f. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

g. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

h. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*

i. Minnesota: The aforementioned practices by Defendants were and are in

violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

j. Mississippi: The aforementioned practices by Defendants were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*, in that, *inter alia*, Mississippi consumers are forced to purchase Singulair from Mississippi pharmacies and vendors at supracompetitive prices;

k. Nebraska: The aforementioned practices by Defendants were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;

l. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq*. in that, *inter alia*, Nevada consumers are forced to purchase Singulair from Nevada pharmacies and vendors at supracompetitive prices;

m. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

n. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq*., and the

New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

o. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

p. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

q. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*, and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

r. Tennessee: The aforementioned practices of Defendants were and are in violation of the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*, in that the conduct complained of had substantial effect on Tennessee commerce in that Tennessee consumers are forced to purchase Singulair from Tennessee pharmacies and vendors at supracompetitive prices;

s. Utah: The aforementioned practices of Defendants were and are in violation of the Utah Trade Practices Act, Utah Code Ann. §§ 13-5-1, *et seq.*, the Utah Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1,

et seq., and the Utah Antitrust Act, Utah Code Ann. § 76-10-919;

t. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

u. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*; and

v. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*, and has substantially affected the people of Wisconsin and has had substantial impacts within Wisconsin in that Wisconsin consumers are forced to purchase Singulair from Wisconsin pharmacies and vendors at supracompetitive prices.

132. Defendants' anticompetitive and unconscionable conduct had substantial impact in each of the Indirect Purchaser States, as Plaintiffs and the members of the Indirect Purchaser States Class purchased or reimbursed purchases of Singulair at prices higher than they would have been absent the conduct in each state.

133. As a result of the conduct described above, Plaintiffs and the members of the Indirect Purchaser States Class have sustained and will continue to sustain substantial losses and damage to their businesses and property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of Singulair, and paying prices for such products that were higher than they would have been but for Defendants' improper actions. The full amount

of such damages is presently unknown and will be determined after discovery and upon proof at trial. Plaintiffs and the members of the Indirect Purchaser States Class seek damages, multiple damages, treble damages, and penalties as permitted by state law for their injuries caused by these violations pursuant to these statutes.

134. Plaintiffs and the members of the Indirect Purchaser States Class also hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition through the scheme set forth herein is unlawful. Plaintiffs and the members of the Indirect Purchaser States Class further seek equitable and injunctive relief to correct for the anticompetitive market effects and other harms to purchasers caused by the unlawful conduct of Defendants, and other relief so as to assure that similar conduct does not occur in the future.

COUNT III
FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS

135. Plaintiffs repeat and re-allege the preceding and subsequent paragraphs as though set forth herein.

136. As a result of their unlawful conduct described above, Defendants have been, and will continue to be, unjustly enriched. Specifically, Defendants have been unjustly enriched, to the detriment of Plaintiffs and the Classes by the receipt of, at a minimum, unlawfully inflated prices and/or illegal monopoly profits on their sale of Singulair.

137. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for Singulair made by Plaintiffs and the Classes.

138. Plaintiffs and members of the Classes are entitled to the amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiffs

and the Classes are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiffs and the members of the Classes may make claims on a *pro rata* basis.

DEMAND FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court:

a. under Count I, determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure;

b. under Count II, determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, injunctive, and equitable relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages;

c. under Count III, determine that this action may be maintained as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages;

d. declare Plaintiffs as representatives of the Classes certified under Counts I, II, and III;

e. after certification, under Count I, declare, adjudge, and decree the conduct alleged herein to be in violation of the Sherman Act and enjoin Defendants from continuing the illegal activities alleged herein;

f. after certification, under Count II, declare, adjudge, and decree the conduct alleged herein to be in violation of the statutes set forth above, enjoin Defendants from continuing the illegal activities alleged herein and award Plaintiffs and each member of the Class damages and, where applicable,

treble, multiple, and other damages, according to the laws of the Indirect Purchaser States, including interest;

g. after certification, under Count III, declare, adjudge, and decree the conduct alleged herein to be in violation of the common law of unjust enrichment and award Plaintiffs and each member of the Class the amounts by which Defendants have been unjustly enriched;

h. award Plaintiffs and the Classes their costs of suit, including reasonable attorneys' fees and expenses as provided by law;

i. grant Plaintiffs and the Classes such other and further as the Court deems necessary and just.

JURY DEMAND

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, on all issues so triable.

Respectfully submitted,

Dated: August 12, 2009

By: */s/ David J. Cohen*

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